Workshops on TB Pharmaceutical Management:

Trip Report Sondalo, Italy and Tbilisi, Georgia July 6-17, 2005

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is a nonprofit organization
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Rational Pharmaceutical Management Plus
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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

A regular supply of TB medicines is one of the main components of the DOTS and DOTS Plus schemes. RPM Plus contributes to these schemes through facilitation of training workshops in collaboration with other TB partners. In July 2005 RPM Plus participated in two training activities for pharmaceutical management of tuberculosis in Sondalo, Italy in collaboration with World Health Organization and in Tbilisi, Georgia in collaboration with GOPA/German Development Agency. There were 12 participants in the Sondalo workshop and 9 participants in the Tbilisi workshop representing the entire Caucasus region.

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Key Words

tuberculosis, TB, pharmaceutical management, FDC, MDR-TB, DOTS, DOTS Plus, pharmaceutical sector assessment

Contents

Acronyms

DOTS	WHO scheme for controlling TB in national programs
DOTS Plus	Projects to control multi-drug resistant TB which are built on a good DOTS scheme
FDC	Fixed dose combination products
GLC	Green Light Committee
GOPA	German Technical Development Cooperation/Consulting Agency
MDR-TB	Multi-drug resistant tuberculosis
TB	Tuberculosis
USAID	U.S. Agency for International Development
WHO	World Health Organization

Background

With the rate of tuberculosis (TB) cases continuing to surge in many developing countries, the need for good pharmaceutical management becomes evident since the WHO schemes, DOTS and DOTS Plus for promoting national TB control demand an uninterrupted supply of quality TB medicines and supplies. Developing countries often lack technical resources to put effective pharmaceutical systems in place.

WHO and other TB partners promote training workshops in national TB control such as the ones held throughout the year in Sondalo, Italy. RPM Plus contributes to the global TB control effort by providing practical training during such workshops in TB pharmaceutical management.

At local levels RPM Plus also provides technical training in target areas and for the past two years has worked with the TB programs of Armenia, Georgia, and Azerbaijan of the Caucasus region to develop appropriate TB pharmaceutical management systems. Following a week long workshop in July 2004, it became evident that an assessment of the systems in the three Caucasus countries is needed. Along side its local TB partner GOPA (German Development Consulting Agency) RPM Plus developed a plan to train target personnel from the pharmaceutical and TB programs in the quick assessment technology developed by RPM Plus. The workshop was planned and carried out in Russian language in Tbilisi, Georgia from July 12-15, 2005. The workshop activities, outcomes and next steps are described in the report below. The assessment workshop was co-funded by USAID through the RPM Plus program (USAID/ENE funding) and GOPA. Thomas Moore was the workshop facilitator in both Sodalo and Tbilisi.

Scope of Work for Caucasus region

The Scope of Work is as follows:

1. Work with participants of Georgia, Armenia and Azerbaijan
2. Establish tracer drug lists specific to the TB programs of each country
3. Develop sample plan for each country
4. Train participants how to:
    a. use PMTB data collection forms
    b. use PMTB Excel Spreadsheet for data entry
    c. clean data recorded on data collection forms
    d. calculate indicators of findings once data are entered
    e. interpret findings as strengths and weaknesses of the TB pharmaceutical management system
5. Brief/debrief USAID/Georgia officials, upon request

Activities

1. Work with participants of Georgia, Armenia and Azerbaijan

There were three participants from each of the three countries, a pharmacist, a TB program doctor and the GOPA representative giving a total of nine participants in all. The three persons will make up the TB pharmaceutical management system assessment team in their country.

Thomas Moore presented a short Power Point presentation on the Pharmaceutical Management for TB Assessment Tool previously developed and tested in several RPM Plus countries like India, Congo Brazzaville, Moldova, China, Ethiopia and Indonesia. The presentation included an introduction to tracer drug development, selection of survey sites, methodology to be used, sample size selection and adaptation of the data collection forms to the local situation.

RPM Plus had previously requested that each participant bring with them information about TB medicine flow, treatment regimens used, layout of TB treatment facilities and knowledge of the recording system used to document TB medicine distribution and use in their countries. The information brought by participants was used in the various activities below.

2. Establish tracer drug lists specific to the TB programs of each country

This is the first important step in preparing for a TB pharmaceutical system assessment since the medicine and supplies list appears on most survey forms. Participants had to develop this list taking into account the types of treatment facilities to be surveyed, the standard treatment regimens for different categories of TB and if treatment personnel are doctors, nurses or other types of health workers. It is noted that the majority of medicines for the three countries are grants from the Global TB Drug Facility (GDF) and are therefore they are fixed-dose combination products. Starting next year Global Fund (GFATM) grants will be used to purchase the GDF medicines.

3. Develop sample plan for each country

With the tracer drug lists in hand the participants were asked to identify the number and types of different TB treatment facilities in their countries, their geographic locations, if there were any special needs or target populations such as HIV hot spots, refugees, etc. Participants were trained how to choose representative treatment facilities (target: 20) taking into account that the entire survey must include a review of at least 600 patient records and all tracer drug/supplies stock records in central and local medical stores and must be representative of both urban and rural TB medicine distribution and use. Finally participants were taught how to use the interval randomized method for sampling and site selection.

4. Train participants how to use PMTB data collection forms, use PMTB Excel Spreadsheet for data entry, clean data recorded on data collection forms, calculate indicators of findings once data are entered, interpret findings as strengths and weaknesses of the TB pharmaceutical management system

Once tracer drug lists and sampling were finalized the participants studied each of the seven different data collection forms and with technical assistance from RPM Plus adapted the tools to their local situations (medicines, supplies, facility types, questions asked, etc). Much discussion took place on whether to survey to determine which TB drugs are being sold to patients in private pharmacies and how much they cost. In the end all three countries decided this information would be useful and will include it in their assessments.

Practice sessions were conducted where participants filled in data on each data collection form and then completed the data collection task by calculating indicators.

RPM Plus then introduced the Excel spreadsheet it has developed for entering data for final analyses. Participants practiced with each data entry form using the practice information they had filled-in in the previous exercise. They also examined the indicator calculation cells to better understand the impact if data entry is done in an incorrect way.

These exercises gave an excellent opportunity to discuss how to clean the data which means to weed out *un-useful* from *useful* data for final analysis. If data are somewhat different from what is supposed to be entered on the data collection forms the TB assessment teams know they must make a decision about including or not including information from that particular form and that they must document their decision for later inclusion in the final report. After much discussion on the topic participants now understand that the best way to avoid excessive data cleaning is the following:

- Thoroughly train data collectors including one-on-one and practical training
- Have data collectors go to a pilot site, fill in the data and then have the TB pharmaceutical assessment team correct any errors in their understanding and judgment on how to use the forms before continuing with the survey
- Train data collectors to stop and review each data collection form for missing or incomplete information before leaving the health facility
- Train data collectors to make comments on appropriate survey forms if conditions for data collection prohibit them from entering data as they were trained

The last discussion of the workshop included analysis and interpretation of the data and report writing. Final data interpretation will take place during a follow-on workshop in the Caucasus region later in 2005 once the assessments are completed. RPM Plus showed participants the resources in the PMTB

assessment manual on these topics. In preparation for the next follow-on workshop, participants were asked to write a draft report of findings including an executive summary, introduction and background, methodology used, numbers and locations of surveyed sites, description of data collectors, indicator results and other specific findings, and recommendations for improving any gaps or weaknesses found in TB pharmaceutical management in their respective TB programs. See Annex 1 for list of participants.

5. Brief/debrief USAID/Georgia officials, upon request

   Thomas Moore briefed Dr. George Mataradze USAID/Georgia by email after the activity was completed.

Collaborators and Partners

Dr. Cornelia Henning, GOPA Georgia
Dr. Maia Kavtaradze, GOPA Georgia

Next Steps

- RPM Plus will provide remote technical assistance for data entry, data review, analysis, calculation of indicators, data interpretation and report writing. GOPA representatives in each country will serve as liaison for the NTP personnel and will request RPM Plus technical assistance when needed via email.
- A follow-on TB pharmaceutical management workshop will be scheduled later in 2005 once the three countries have finalized data collection, data entry, analysis and draft report writing
- Thomas Moore will prepare an article for the Caucus's TB Newsletter explaining this activity. (Note: this was prepared and sent to GOPA/Georgia by email on 20 July 2005). See Annex 2 to review the article in English.

Outcomes

Participants will be familiar with techniques for conducting program research and be able to use these new skills in their countries. Also RPM Plus has suggested to participants that the final reports written by each of the three TB assessment teams should be used for the following:

- Present to NTP manager for follow-up on aspects related to drug availability and use
- Present to MoH for knowledge and action-taking to improve strengths and weaknesses in the TB pharmaceutical management system
- Present to local and International TB partners to encourage support for improving gaps and weaknesses identified by the survey
- Use in future grant application writing such as to the Global Fund to Fight Aids, TB and Malaria, the Green Light Committee and the Global TB Drug Facility to describe their needs

Annex 1: Tbilisi, Georgia Workshop Participants

Armenia-NTP	GASPARYAN Nelly
Armenia-NTP	Dr. MAZKOSSIAN Laura
Armenia-GOPA	BABYAN Mariam
Azerbaijan-NTP	ASADOVA Yegana
Azerbaijan-NTP	Dr. ALAMAEDOVA Svetlana
Azerbaijan-GOPA	Dr. YEZALOV Ogtay
Georgia-NTP	BICHASHVILI Eliso
Georgia-NTP	SIKHAZULIDZE, Rusudan
Georgia-GOPA	Dr. KAVTARADZE Maia

Annex 2: Caucus's TB Newsletter Article about The Workshop

With the rate of tuberculosis (TB) cases continuing to surge in the Caucasus, the need for good pharmaceutical management becomes evident since the WHO schemes, DOTS and DOTS Plus for promoting national TB control, demand an uninterrupted supply of quality TB medicines and supplies. To that end the NTPs of Georgia, Armenia and Azerbaijan are conducting an assessment of the TB pharmaceutical sectors in their countries to find any gaps or weaknesses affecting their programs. TB partners GOPA and Management Sciences for Health (supported by USAID through its RPM Plus program) are providing support for the activities.

A training workshop for data collectors and survey managers from each of the three countries took place in Tbilisi from 12-15 July 2005. The assessment materials being used in this activity were developed and field tested in many countries by Management Sciences for Health who also provided the workshop facilitator, Thomas Moore.

During the workshop participants analyzed and developed a list of TB medicines and supplies they will survey in storage and treatment facilities of their NTP programs. Participants also selected the sites where data will be collected, adapted data collection forms to their country TB program situations, practiced calculation of indicators and entering of data into databases which will be used for data analysis. In most cases the data will be collected during routine supervisory visits that are a normal part of the national TB programmes. Private sector pharmacies will also be surveyed.

With these data in hand each of the three countries will prepare an individual country report of findings and discuss strengths and weaknesses of their TB pharmaceutical management systems. The draft reports will then be discussed during a follow-on workshop later in 2005 supported by GOPA and MSH to assure that complete interpretation of the data has been done.

With these reports, NTP managers, Ministers of Health, and TB partners can apply for TB grants from international organizations such as the Global TB Drug Facility, Green Light Committee and Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM). Having learned basic techniques for conducting program research, participants in this activity will be able to carry out other types of surveys as well.

Workshop Participants

Armenia-NTP	GASPARYAN Nelly
Armenia-NTP	Dr. MAZKOSSIAN Laura
Armenia-GOPA	BABYAN Mariam
Azerbaijan-NTP	ASADOVA Yegana
Azerbaijan-NTP	Dr. ALAMAEDOVA Svetlana
Azerbaijan-GOPA	Dr. YEZALOV Ogtay
Georgia-NTP	BICHASHVILI Eliso
Georgia-NTP	SIKHAZULIDZE, Rusudan
Georgia-GOPA	Dr. KAVTARADZE Maia

Scope of Work for WHO TB consultant training workshop in Sondalo, Italy

Background: Purpose of the visit was to facilitate presentations and practical work on TB Pharmaceutical Management for participants of the WHO TB Consultant Training Course in Sondalo, Italy on July 7-10, 2005. The participation of Thomas Moore who facilitated the pharmaceutical management activity was funded by USAID through the RPM Plus program (SO5 TB funding). All other costs including those of participants were funded by WHO.

Activities

RPM Plus participated in the WHO consultant training course in Sondalo, Italy from July 7-10, 2005. Thomas Moore made Power Point presentations to the 12 participants in attendance (see Annex 1 for list). The presentation included discussions on TB pharmaceutical management components, stakeholders and potential problems contributing to unavailability of TB medicines for patients, poor quality medicines and irrational patient treatment.

The activity included ample practical work including a case study where participants had to identify weaknesses in TB pharmaceutical management of the country, Fictitia (a larger case study used throughout the TB workshop) and to draft steps that can be taken for improving the noted challenges. The practical exercise gave participants a chance to see what type of recommendations they can make to TB programs after they conduct their WHO assessments. See Annex 2 for the case study materials. To obtain a copy of the Power Point materials please send an email to rpmplus@msh.org Subject: Sondalo presentation.

Annex 1: List of Participants

Dr. Elmira Amathunova	International Committee of Red Cross, Bishkek
Dr. Dumitru Laticevshi	TB/AIDS Programme Manager, Moldova
Dr. Kai Kliiman	NTP, Estonia
Dr. Viorel Soltan	HIV/Aids Programme, Moldova
Dr. Grigory Volchenkov	DOTS Pilot Programme Director, Vladimir, Russia
Dr. Nikita Afnasiev	Senior Health Advisor, USAID, Russia
Dr. Alexander Golubkov	Global Fund Project Coordinator, Tomsk, Russia
Dr. Alina Pascaru	National TB Institute, Moldova
Dr. Maxim Berdnikov	International Committee of Red Cross, TB/HIV, Geneva
Dr. Saleri Nuccia	Infectious Disease Dept, Univ. of Brescia, Italy
Dr. Peter Taliente	Tropical Medicine, Sondalo Hospital, Italy
Dr. Keshab Shrestha	WHO-Nepal country officer, Nepal

Annex 2: Fictitia Case Study—Pharmaceutical Management

Fictitia is facing serious problems in supply and access to sufficient and good-quality drugs. The MOH Drug Regulatory Authority carries out registration and maintenance of Drug Register, accreditation and licensing of pharmaceutical activity, drug quality control and certification. The Pharmacopoeia Committee in the MOH issues permissions for clinical trials and medical use of new drugs for diagnostic and preventive purposes. The Government of Fictitia adopted a law “On Drugs and Pharmaceutical Activity” and “On narcotic, psychotropic substances and precursors”, and on the development and update of a national Essential Drug List (EDL).

Import, manufacturing, sale and use of drugs in Fictitia are only allowed when the drugs are registered by the National Drug Regulatory Authority. Drug registration exists since 1999 in the Republic. Currently 204 drugs manufactured in Country A and B and 179 drugs manufactured in other countries are registered. The majority of registered drugs are manufactured in Afrasia (250 brands), Asia (54 brands) and Europe (54 brands) etc. Among 262 drugs figured in EDL only 69.7% is registered in Fictitia. Furthermore, a major problem with drug registration in Fictitia is the lack of a policy that promotes registration of generic drugs (drugs not protected by patent and produced by the large number of manufacturers) and essential drugs. Due to insufficiently maintained border control and illegally imported drugs a large number of non-registered drugs is still circulating on the market of Fictitia. In 1998 the Essential Drug List of the Popular Republic of Fictitia (EDL) was developed, adopted and will be revised every two years. It includes 262 items and 15 medical supplies. However, awareness of the essential drugs concept in health facilities remain low. Drug quality control in Fictitia is performed by the quality control laboratories in the Ministry of Health. However the existing laboratories do not comply with modern requirements and GMP. Establishing of a National Drug Quality Control Laboratory is needed at present stage, but it will require considerable investments.

Majority of drug are provided by the humanitarian aid. Fictitia has received drug donations since 1994 from the International Community. For the last years a trend to constant decrease of humanitarian aid is observed. The “Guidelines on donation of pharmaceuticals and other medical products of Fictitia” was developed, which is considered to be the principle document regulating drug donations in Fictitia. The Guidelines are based on WHO principles.

The government budget allocated for drug procurement is generally determined on the basis of available resources without taking into account real drug needs. Drug procurement is carried out by Ministry of Health, Department of Essential Drugs through Fictitia-Indofria Joint Venture "Fictik Pharma Ltd." or the “Fictitian Drug Manufacture” or through international bidding process. Drug are stored in the Central Medical Store and in country drug delivery is done by the Central Medical Store directly toward 59 operational district 2 to 4 times per years.

Licensing and accreditation procedures for private pharmaceutical and drug sellers have been implemented in Fictitia since 1992. However, increasing number of pharmacies without licensing has been observed in large cities of Fictitia. Inspection and control regulating drug quality and pharmaceutical activity and applying sanctions and penalties does not exist in Fictitia. Numerous cases of unregistered, doubtful quality

drugs or drugs with expired shelves-life have been detected, as well as drugs without quality certificate. Professional training of inspectors adjusted to the new economic conditions should also be given particular attention.

Currently drug information is mostly provided by manufacturers and, therefore, has subjective and advertising characteristics. Doctors and pharmacists do not have access to up-to-date literature. Therefore a lack of objective drug information on contraindications, side effects and compatibility with other drugs is observed. A National Drug Formulary, which can serve as important source of objective information on Essential Drugs for all health workers of the country, has not been developed so far in Fictitia. The constant mechanism of side effect case detection and monitoring is also absent.

A survey on drug prescribing habits in Fictitia showed that on average 2.67 drugs are prescribed per prescription by PHC nurses. Only 60% of prescribed drugs are generic, indicating inefficient prescribing practices. Antibiotic use, in 41% of all prescription impresses as being rather high, and use of injection, being found in 48% of all prescriptions, is likely to be much higher than justifiable for primary health care needs. Equally serious is the fact that only 66% of all prescribed drugs are figured in the EDL. Only a limited number of standard treatment guidelines are used in primary health care practice (acute respiratory diseases, diarrhoea, TB, malaria). Therapeutic Drug Committee under the MoH has been just established. Self-medication is widely practised in Fictitia as a result of uncontrolled increase of the number of drugs, which can be obtained without prescriptions in private pharmacies and on markets. Apart from leaflets patients do not have any additional information on drug use. In public health facilities medicines, if available, are distributed free of charge only to vulnerable groups of the population. The average treatment cost per patient is 5,096 FF (2.6 USD[6, 7]). When drugs are not available, patients are asked to bring them from private pharmacies on their own cost.

Private sector

The private sector is rapidly growing in an uncontrolled way, even though large-scale private sector investment has not yet taken place. The commercial health sector is characterised by large numbers of small, under-capitalised institutions and practices, which appear to be marginal economy. The commercial health sector is poorly organised, anarchic, and any of its leaders are suspicious of government intervention and regulation. Staffing of the private sector appears to be largely of individuals who also work in the public sector during public working hours.

In 2002, the number of registered private clinics, laboratories is 330 units in which there are only 395 beds in total. Nevertheless, around 500 illegal pharmacies were found by the MOH. Some media agencies advertise medical services and pharmaceutical products using misleading information

Tobacco and alcohol advertising in Fictitia is increasingly aggressive. In 1999, street sign survey along 18 main streets in South City found that 39% of 35,954 street signs advertised cigarettes and alcohol. Legislation of food safety is being prepared.

Legal and regulatory reform is needed, particularly in the area of certification, registration and supervision of private sector medical practitioners and medical facilities including pharmacies and drug sellers. The law on pharmaceutical management exist and need to be reinforced. The MOH is preparing a law code of medical conduct.
At village level, there are many types of traditional healers, including traditional birth attendants (TBA). The traditional healers who employ spiritual and herbal remedies are often consulted, particularly when diseases are believed to be supernatural origin.

Health financing

An inadequate supply of funds remains a major obstacle in implementing the policy of the Ministry of Health at all levels of the health system. The three main sources of finance for health sector are government budget funded by general tax revenues, donor funds and local community (see table 7). There are various agencies supporting the health sector and general consensus to support the coverage plan, but there is not a common strategic and financial framework for the sector. As a result, there is a proliferation of projects and disease based programmes and the distribution of external resources is very uneven, with high concentration in South City and nearby provinces to the neglect of more remote areas. The Ministry of Health is considering development of Sector Wide Approach to agree the strategies for the sector. This requires close working with funding agencies.

The amount of out of pocket expenditure on health in Fictitia is very high – about 10% of rural expenditure is for health; among the poorest this rises to 20%. This is unusually high and becomes a common co-cause of poverty.

The Ministry of Health is working hard to improve the utilisation of both government budget and donor funds to be effective, and at the same time developing cost-sharing partnerships with local communities through user fees. In March 1999, a law on medical services was adopted by the National Assembly to legalize out-of pocket payments for the bulk of health care services provided to all non-vulnerable and non-targeted groups of population. Various other initiatives are being tested, including contracting service management out to NGOs, contracting delivery of the whole district out, and decentralising financial management. The health sector is a pilot for public administration reform, which provides an opportunity to address systemic budget and staff problems in the sector. The MOH is also developing initiatives with the private sector including a scheme to certify providers which offer a defined quality of care.

As yet, there is no effective insurance system in operation in Fictitia, either statutory or voluntary. There are few private companies, which provide voluntary insurance health programmes. In 2004 the system of compulsory medical insurance based on MPS will be tested in a step by step fashion in limited area (one district). Preconditions for the establishment of the medical insurance system include: political decision, effective rationalization of health care, specification of specific health programmes to be covered by the government budget and establishment of a co-payment structure for activities of secondary importance, and specification of premium rates and conditions for the systems' financial stability. Insurance coverage and premium rates and collection should be differentiated according to principal population groups (working population, self-employed, dependants, vulnerable groups etc with appropriate arrangements for

non-paying groups. Arrangements should be made to ensure timely and complete collection of premiums, and hence financial stability of the system.

Compulsory insurance is to be provided by a Compulsory Medical Insurance Fund, which is to contract with MPS providers specified in the insurance programme. Government will undertake payment of premium contributions on behalf of the non-paying groups. Socially vulnerable groups are to be defined and could include: disabled persons (according to degree of disability), children under 18 with one parent, orphans under 18, TB leprosy and AIDS patients etc.

Table 7: main sources of finance for health sector

Funding source	Public sector	Private sector
Ministry of health including bank loan US$ per capita	3.1	
Donor agencies, US$ per capita	1.9	Pilot testing of contracting model in 3 districts and compulsory insurance in one district
House hold	9.5	

Fictitia has shown its commitment in increasing annual budget for 2002 and the Ministry of Health has developed a budget allocation formula based on per capita basis with adjustment for the relative levels of disadvantage in each province and district. However, unstable politic in the 90s and limited economic capacity has resulted in the government budget devoted to health remaining at only 3.1 US$ per capita per year. Economic problems and competing government priorities have meant that health managers have been unable to access the full budget approved by the government and national parliament. This problem has particularly occurred at the provincial level where the annual budget implementation is most places is only 40%

The financial management capacity of health managers has been strengthened through training on the accounting system and budget expenditure report system. The priority now is to restore government management at provincial and district in order to ensure monthly expenditure and to explore ways to make the current expenditure system to be more efficient and effective.

Donor funded investment and support to the health sector remains considerable. However, donor assistance is not distributed equitably. Some remote province such as Yahoo and Stelvio have been neglected by most potential donors and lending agencies including UNICEF, WHO, bilateral agencies, World Bank and Afrasian Development Bank